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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,488	12/14/2001	Paul Clayton	02481.1769	1028

7590 03/23/2004

Finnegan, Henderson, Farabow,
Garrett & Dunner, L.L.P.
1300 I Street, N.W.
Washington, DC 20005-3315

EXAMINER

KIM, JENNIFER M

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 03/23/2004

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/014,488

Applicant(s)

CLAYTON, PAUL

Examiner

Jennifer Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3,4,6,9,11,13,15,17,20,22,24,25,27,29,32 is/are allowed.
- 6) ☒ Claim(s) 2,5,7,8,10,12,14,16,18,19,21,23,26,28,30,31 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/21/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The response filed on August 22, 2003 have been received.

Action Summary

The rejection of claims 1-33 under 35 U.S.C. 103(a), over Kosbab (WO 98/33494) in view of Gilles (U.S. Patent No. 6,248,375B1) and further in view of Arbiser (US Publication 2001/0025034A1) is hereby expressly withdrawn in view of Applicant's response.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 5, 10, 16, 21, 28 and 33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the "treat" the diseases set forth in the claims, does not reasonably provide enablement for the "prevent" and "cure" the diseases set forth in the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

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3. Enablement is considered in view of the Wands factors (MPEP 2164.01(a)).

These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, state of the prior art and the amount of experimentation necessary. All of the **Wands factors** have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: All of the rejected claims are drawn to a composition used to prevent, cure, or treat diseases set forth in claims 5, 10, 16, 21, 28 and 33 comprising effective amounts of various active agents. The nature of the invention is extremely complex in that it encompasses the actual prevention and curing the disorders (i.e. diabetes, osteo-arthritis, osteoporosis, asthma, mental decline age-related eye disorders) such that the subject treated with above composition does not contract diabetes, osteo-arthritis, osteoporosis, asthma, mental decline, age-related eye disorders.

Breath of the Claims: The complex of nature of the claims greatly exacerbated by breath of the claims. The claims encompass prevention and curing a complex disorders which has potentially many different causes (i.e. many different mutations and allergens or combination of mutations and allergens). Each of which may or may not be addressed by the administration of the claimed composition.

Guidance of the Specification: The guidance given by the specification as to how one would administered the claimed composition to a subject in order to

actually prevent and cure the disorders such as diabetes, osteo-arthritis, osteoporosis, asthma, mental decline age-related eye disorders is minimal. All of the guidance provided by the specification is directed towards treatment rather than prevention or curing of the disorders.

Working Examples: All of the working examples provided by the specification are directed toward the treatment rather than prevention or curing of the disorders (i.e. diabetes, osteo-arthritis, osteoporosis, asthma, mental decline age-related eye disorders).

State of the Art: While the state of the art is relatively high with regard to treatment of the disorders (i.e. diabetes, osteo-arthritis, osteoporosis, asthma, mental decline age-related eye disorders), the state of the art with regard to prevention or curing of such disorders is underdeveloped. In particular, there do not appear to be any examples or teachings in the prior art wherein a compound similar to the claimed composition was administered to a subject to prevent and to cure the development of the disorders.

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to the actual prevention and curing of the disorders in a subject with the claimed composition makes practicing the claimed invention unpredictable in terms of prevention and curing of disorders.

The amount of Experimentation Necessary: In order to practice claimed invention, one of skilled in the art would have to first envision a combination of appropriate pharmaceutical carrier, compound dosage, duration of treatment,

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route of administration, etc. and appropriate animal model system for one of the claimed compositions and test the composition in the model system to determine whether or not the composition is effective for prevention or curing the disorders. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regard prevention and curing of the disorders with any composition, one of skill in the art would have to then either envision a modification of the first combination of pharmaceutical compound, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system, or envision an entirely new combination of the above, and test the system again. If again unsuccessful, which is likely given the lack of significant guidance from the specification of prior art regarding prevention or curing of the disorders with any composition, the entire, unpredictable process would have to be repeated until successful. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention to prevent or cure the development of diabetes, osteo-arthritis, osteoporosis, asthma, mental decline and age-related eye disorders in a subject by administration of one of the claimed composition.

Therefore, a composition to prevent, cure diabetes, osteo-arthritis, osteoporosis, asthma, mental decline age-related eye disorders is not considered to be enabled by the instant specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 7, 8, 12, 14, 18, 19, 23, 26, 30 and 31 are rejected under 35

U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "additional substances" renders the claims indefinite since it is not clear what are the additional substances to be employed in the composition since the term is not defined in the specification and without out any examples.

Allowable Subject Matter

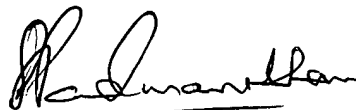
Claims 1, 3, 4, 6, 9, 11, 13, 15, 17, 20, 22, 24, 25, 27, 29 and 32 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
March 16, 2004